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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                  | CONFIRMATION NO.       |
|---|-------------|----------------------|--------------------------------------|------------------------|
| 10/697,486  | 10/30/2003  | George Gullickson    | P-11191.00                           | 7401                   |
| 27581   | 7590        | 05/21/2007           |                                      |                        |
| MEDTRONIC, INC.<br>710 MEDTRONIC PARKWAY NE<br>MINNEAPOLIS, MN 55432-9924 |             |                      | EXAMINER<br>PAPAPIETRO, JACQUELINE M |                        |
|   |             |                      | ART UNIT<br>3739                     | PAPER NUMBER           |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/697,486

Applicant(s)

GULLICKSON ET AL.

Examiner

Jacqueline Papapietro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05 Aug 2004</u>   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Objections*

Claims 1-26 are objected to because of the following informalities: Claim 1 recites the limitation "the elongated guide track" which lacks proper antecedent basis in the claims. Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo (US 6530897 B2).

Regarding claims 1-9 and 14-23, Nardeo discloses a steerable catheter comprising: an elongated catheter body (100, Fig 7) including a proximal end, a distal segment (Fig 1) and a deflection lumen extending from the proximal end toward the distal segment (15, Figs 1 and 2); a handle (200, Fig 7) coupled to the catheter body proximal end and including a longitudinal axis; and a deflection mechanism (220) for selectively inducing a bend in the catheter body; the deflection mechanism comprising: an elongated deflection wire (50) extending within the deflection lumen of the catheter body and into the handle; a thumb wheel (steering dial 220) mounted within the handle; wherein rotation of the thumb wheel in a first direction moves the deflection wire proximally through the deflection lumen inducing a first bend of the catheter body, and a rotation of the thumb wheel in a second direction moves the deflection wire, inducing a second bend of the catheter body (column 4 lines 63-66); wherein the handle further includes a first major side (213, Fig 6) and a second major side (214) and the thumb wheel is disposed intermediate the first major side and the second major side (see Fig 6); wherein the handle further includes a first handle body portion and a second handle body portion joined along a plane substantially perpendicular to the thumb wheel axis;

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the first handle body portion and the second handle body portion capturing the thumb wheel there between (see figs 6-8); wherein the deflection mechanism further comprises a securing mechanism (locking device 230, Fig 7) selectively engageable in use from either the first major side or the second major side of the handle to apply a friction force, which holds the thumb wheel preventing further rotation of the thumb wheel (column 5 lines 23-29); wherein the handle further includes a first minor side (215, Fig 7) extending between the first major side and the second major side and a first thumb wheel window (218) extending through the first minor side through which a portion of the thumb wheel is exposed (see Figs 6-8); wherein the handle further includes a second minor side opposite the first minor side (216, Fig 7), and a second thumb wheel window (see Figs 7 and 8) extending through the second minor side through which a second portion of the thumb wheel is exposed, wherein the thumb wheel includes a side wall forming an outer rim, the outer rim being exposed through the first thumb wheel window (see Figs 7-8) and the second thumb wheel window, wherein the outer rim includes serrations (222, Fig 7) and first and second indentations (any of the indentations formed by teeth 222, see Fig 7).

Nardeo discloses a deflection mechanism wherein rotation of the wheel is translated into a forward-and-back motion of the deflection wire. Nardeo also discloses that the wire may terminate on a gear or other device mechanically controlled by the motion of the thumb wheel (column 4 line 67- column 5 line 2). Nardeo does not specifically disclose a guide track, rack arm, runners, pinion gear, or linear rack. However, at the time the invention was made it would have been an obvious matter of

design choice to a person of ordinary skill in the art to substitute a deflection mechanism including a guide track, pinion gear, and rack arm for the deflection mechanism disclosed by Nardeo because Applicant has not disclosed that the deflection mechanism of the instant application is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the deflection mechanism of Nardeo or the deflection mechanism of the instant application because both mechanisms translate rotational movement to linear movement in order to pull the deflection wire and to induce a bend in the catheter body. Therefore, it would have been an obvious matter of design choice to modify Nardeo to obtain the invention as specified in claims 1-9 and 14-23.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo as applied to claim 9 above, and further in view of Thompson et al (US 5358478).

Nardeo discloses the catheter of claim 9, as described above, but does not disclose a resilient compressible member. Thompson teaches a steerable catheter (10) with a thumb wheel (18 and 34, Fig 1), deflection wire (58), and deflection mechanism (Fig 2) comprising a securing mechanism (locking lever 38, Fig 1) selectively engageable to apply friction, which holds the thumb wheel and prevents rotation of the thumb wheel (column 4 lines 10-24). The securing mechanism comprises a resilient compressible member (an O-ring) disposed in the gap between the thumb wheel

sidewall and one of the first major side and the second major side of the handle body (column 4 lines 13-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the locking mechanism of Thompson in the catheter of Nardeo in order to prevent rotation of the wheel when no further bending of the catheter is desired.

Regarding claims 11-13, where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPW 7, 9 (CCPA 1975). Applicant has not disclosed that the securing mechanism of the instant application is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the securing mechanism of Nardeo or Thompson, or the securing mechanism of the instant application because both mechanisms successfully stop the thumb wheel from further rotation. Therefore, it would have been an obvious matter of design choice to modify Nardeo to obtain the invention as specified in claims 11-13.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo as applied to claim 1 above, and further in view of Biggs (US 6030360).

Nardeo discloses the catheter of claim 1, with the features described above, wherein the handle is ergonomically designed (column 4 lines 51-52), but does not specifically disclose a narrowed waist. Biggs teaches a steerable catheter wherein a

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handle includes a first major (312U, Fig 1B) side and a second major side (312L); the first and second major sides forming a thumb wheel support segment and a grasping segment extending proximally from the support segment (see Figs 1A-2B); the grasping segment including a narrowed waist (see Fig 2A) facilitating ergonomic handling. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the narrowed waist of Biggs in the steerable catheter of Nardeo in order to make it easier and more comfortable for the user to hold the instrument.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.




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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMP

Jacqueline Papapietro  
Art Unit 3739



LINDA G. M. DVORAK  
SUPERVISORY PATENT EXAMINER  
GROUP 3700